

Declaration of Conformity

Doc.No.:FN-QS9.3-WTD01-COM0730 Rev.00

Manufacturer:	Finess Healthcare Group Co.,Ltd No.1503 A1 Block,No.203 Lantian Road 315000 Ningbo PEOPLE'S REPUBLIC OF CHINA
European Representative:	ZOUSTECH S.L. Pso. Castellana,141-Planta 19, 28046 Madrid, SPAIN
Product Name	Non Sterile Wooden Tongue Depressor
Model Number:	FN-WTD010102
UMDNS-Code:	14066

Classification (MDD, Annex IX): Class I Non Sterile Rule 5

Conformity Assessment Route: **Annex VII**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Manufacturer takes full responsibility of the content of Declaration of Conformity.

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC

Harmonized Standards:

EN ISO13485:2016 EN ISO15223-1:2016 EN ISO14971:2019

EN1041:2008+A1:2013

Signature: *Michelle-Z*

Name:Michelle Zhang

Place& Date: Ningbo 2020-01-01

Position: Management Representative